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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,978	02/14/2002	Ken Hassen	219671US0CONT	6080

22850 7590 04/15/2003

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 04/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/073,978	HASSEN, KEN	
	Examiner	Art Unit	
	Susan Tran	1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 31 March 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☒ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-14*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

ATTACHMENT

Receipt is acknowledged of applicant's Request for Extension of Time, Declaration 1.132, and Request for Reconsidered filed 03/31/03.

The period for reply continues to run 3 MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 or a request for a continued examination (RCE) in compliance with 37 CFR 1.114 must be timely filed to avoid abandonment of this application.

Response to Arguments

Applicant's arguments filed 03/31/03 have been fully considered but they are not persuasive. The examiner maintains the original rejections.

Applicant argues that Cavazza I have a particle size such that more than 10% by weight is retained by a 50 mesh sieve and more than 40% by weight is retained by a 100 mesh sieve, and therefore, does not teach the claimed L-carnitine. Contrary to the applicant's argument, applicants' claims do not require (recite) the percentage weight of particle size that can pass through a mesh sieve. Furthermore, applicants' generic claims only require particle size *such that it substantially* passes through a 100 USBS mesh sieve. As pointed out by the applicant's, about 40% by weight of carnitine in

Cavazza I is retained by a 100 mesh sieve, therefore, would it been obvious to one of ordinary skill in the art that the remainder of the carnitine would "substantially" passes through a 100 mess sieve or maybe a finer mesh sieve? Accordingly, absent of showing evidence on the contrary, it is the position of the examiner that Cavazza I teaches carnitine having particle size similar to that of the claimed carnitine.

Applicant argues that Cavazza II cannot cure the basic deficiencies of Cavazza I for the reasons that Cavazza II only using ultrafine L-carnitine in combination with omega-3 fatty acids in fish oil or coenzyme Q10, or alpha lipoic acid to obtain an easily workable mixture. Contrary to the applicant's argument, applicants' claims do not exclude the use of other ingredient, *e.g.*, omega-3 fatty acids in fish oil or coenzyme Q10, or alpha lipoic acid. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, un-recited elements or method steps. Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

The Declaration under 37 CFR 1.132 filed 03/31/03 is insufficient to overcome the rejection of claims 1-14 based upon Cavazza I in view of Cavazza II as set forth in the last Office action because: showing is not commensurate in scope with the claims.

The Declaration stated that "[that] is my opinion that the ultrafine L-carnitine described and claimed in the present application exhibits a number of unexpected

advantages as compared to the L-carnitine described in Cavazza. Nonetheless, the Declaration has not provide any side-by-side data comparing/showing unexpected results over the cited references. Any showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997).

It is Chopra's opinion disclosed in the Declaration that the claimed ultrafine L-carnitine can be used to pack firmly in capsules, thereby leaving very little interstitial spaces between particles, and thus, *this is probably the reason why* these capsules do not exhibit premature: 1) discoloration; 2) development of unacceptable odor; 3) moisture pick-up; and 4) physico-chemical instability. The Declaration is not persuasive for the following reasons: 1) it is Chopra's opinion (and/or speculation); 2) the use of a capsule is not required in the claims ; 3) Cavazza I does teach that L-carnitine can be used to prepare orally administrable dosage form, including, tablet and capsule (column 7, lines 29-55); 4) there is no data showing the capsule taught by Cavazza I would exhibit premature discoloration, development of unacceptable odor, moisture pick-up, and physico-chemical instability.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-

5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
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